

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
State of Montana v. Abbott Labs, Inc., et al.,
D. Mont. Cause No. CV- 02-09-H-DWM

**FUJISAWA HEALTHCARE INC.'S AND FUJISAWA USA INC.'S
ANSWER TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

Defendants Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. (collectively referred to as "Fujisawa"), for its Answer to the State of Montana's Second Amended Complaint (the "Complaint") as follows:

Preface

Prior to addressing the specific allegations of the numbered Paragraphs, Fujisawa states the following general objections and responses to the Complaint as a whole. The Complaint contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine or the joint-defense privilege, Fujisawa reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiff may have in its possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered

by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

The Complaint also improperly and repetitively refers to Fujisawa and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Fujisawa. It also improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Finally, the Complaint includes terms that are undefined and that are susceptible of different meanings.

Notwithstanding these pleading deficiencies, Fujisawa has attempted to respond to Plaintiff's allegations.. To the extent allegations refer to the knowledge, conduct or actions of other entities, Fujisawa is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Fujisawa denies those allegations. Fujisawa also denies each and every allegation contained in the Complaint, except as specifically hereinafter admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations that are contained in any averment or in the Complaint as a whole. Moreover, Fujisawa specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered Paragraphs in the Complaint. These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

I.

1. To the extent that the allegations set forth in Paragraph 1 contain Plaintiff's characterization of the action, no answer is required and none is made. Fujisawa denies the remaining allegations in Paragraph 1 of the Complaint that pertain to it.

2. Fujisawa admits that it is a manufacturer of pharmaceutical products. To the extent the allegations of this Paragraph refer to statutory or regulatory programs, the statutes,

regulations and other sources regarding those programs speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 2 of the Complaint are directed to persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 2 of the Complaint that pertain to it.

3. The allegations in Paragraph 3 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

4. The allegations in Paragraph 4 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

5. Fujisawa admits that some private and public drug reimbursement systems reimburse physicians and pharmacies based upon the AWP as published and reported by various compendia. Fujisawa denies the remaining allegations in Paragraph 5 of the Complaint that pertain to it.

6. Fujisawa generally admits that, historically, the AWP's for Fujisawa's products published by various compendia were based upon pricing data provided by Fujisawa. Fujisawa denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraph 6 of the Complaint. To the extent the allegations in Paragraph 6 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 6

contain legal arguments or conclusions of law, no answer is required and none is made. Fujisawa denies the remaining allegations in Paragraph 6 of the Complaint that pertain to it.

7. Fujisawa denies the existence of, and its participation in, any “AWP Inflation Scheme” as alleged in Paragraph 7 of the Complaint. To the extent the allegations in Paragraph 7 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 7 contain legal arguments or conclusions of law, no answer is required and none is made. Fujisawa denies the remaining allegations in Paragraph 7 of the Complaint that pertain to it.

8. Fujisawa denies the allegations in Paragraph 8 of the Complaint that pertain to it. To the extent the allegations in Paragraph 8 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

9. Fujisawa denies the allegations in Paragraph 9 of the Complaint that pertain to it. To the extent the allegations in Paragraph 9 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

10. Fujisawa denies the allegations in Paragraph 10 of the Complaint that pertain to it. To the extent the allegations in Paragraph 10 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or

information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

11. Plaintiff's "Best Price" claims against Fujisawa have been dismissed by Court Order. Accordingly, no answer is required and none is made.

12. Plaintiff's "Best Price" claims against Fujisawa have been dismissed by Court Order. Accordingly, no answer is required and none is made.

13. Fujisawa denies the allegations in Paragraph 13 of the Complaint that pertain to it. To the extent the allegations in Paragraph 13 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

14. Fujisawa denies the allegations in Paragraph 14 of the Complaint that pertain to it. To the extent the allegations in Paragraph 14 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

15. Fujisawa denies the allegations in Paragraph 15 of the Complaint that pertain to it. To the extent the allegations in Paragraph 15 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

16. Fujisawa denies the allegations in Paragraph 16 of the Complaint that pertain to it. To the extent the allegations in Paragraph 16 of the Complaint refer to the knowledge, conduct or

actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

17. Fujisawa denies the allegations in Paragraph 17 of the Complaint that pertain to it. To the extent the allegations in Paragraph 17 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

18. The allegations set forth in Paragraph 18 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

19. Fujisawa denies the allegations in Paragraph 19 of the Complaint that pertain to it. To the extent the allegations in Paragraph 19 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

20. The allegations set forth in Paragraph 20 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

21. The allegations set forth in Paragraph 21 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

22. The allegations set forth in Paragraph 22 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

23. The allegations set forth in Paragraph 23 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

II.

24. Fujisawa admits that Mike McGrath is the current Attorney General of the State of Montana. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations contain legal conclusions regarding the scope of the Attorney General's statutory authority, no answer is required and none is made. Any characterizations are denied. Fujisawa denies the remaining allegations in Paragraph 24 of the Complaint that pertain to it.

25. Fujisawa avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 25 set forth legal arguments or conclusions of law, no response is required and none is made.

26. Fujisawa generally admits the factual allegations set forth in Paragraph 26 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 26 set forth legal arguments or conclusions of law, no response is required and none is made.

27. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27, and therefore, denies those allegations.

28. Fujisawa generally admits the factual allegations set forth in the first sentence of Paragraph 28 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of Paragraph 28 and therefore, denies those allegations. To the extent the allegations in Paragraph 28 set forth legal arguments or conclusions of law, no response is required and none is made.

29. Fujisawa denies the allegations set forth in Paragraph 29 of the Complaint that pertain to it. To the extent the allegations in Paragraph 29 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations in Paragraph 29 set forth legal arguments or conclusions of law, no response is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

30. Fujisawa admits that it conducted business in the State of Montana.

31-69. The allegations in Paragraphs 31 through 39 of the Complaint are directed to other defendants and require no response from Fujisawa.

70. Fujisawa admits that Fujisawa Healthcare, Inc. is a Delaware corporation with its principal place of business at Three Parkway North, Deerfield, Illinois. Fujisawa also admits that Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation. Fujisawa admits that Fujisawa Healthcare develops, manufactures, sells and/or distributes products in the therapeutic areas of transplantation, anti-infective,

dermatology, and cardiovascular. Fujisawa denies the remainder of the allegations set forth in Paragraph 70.

71. Fujisawa denies the allegations set forth in Paragraph 71.

72. Fujisawa objects to Plaintiff's collective reference to the "Fujisawa Group."

73. Fujisawa admits that it manufactures drugs that are reimbursed under the Montana Medicaid Program. Fujisawa denies the remainder of the allegations set forth in Paragraph 73.

74-111. The allegations in Paragraphs 46 through 111 of the Complaint are directed to other defendants and require no response from Fujisawa.

III.

112. The allegations in Paragraph 112 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

113-121. The allegations set forth in Paragraphs 113 through 121 are alleged findings, opinions, statements or conclusions contained in the "Chartbook," "Chartbook Update" and "Fact Sheet" cited in Paragraphs 113 through 121 of the Complaint. Fujisawa avers that those sources cited in Paragraphs 113 through 121 are the best evidence of their contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations and demands strict proof thereof.

122. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122 and, therefore, denies those allegations.

123. Fujisawa denies the allegations set forth in Paragraph 123 of the Complaint that pertain to it.

IV.

124-141. The allegations set forth in Paragraphs 124 through 141 contain Plaintiff's self-serving conclusions and generalizations regarding the Prescription Drug Market without specific detailed factual allegations averred against Fujisawa. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof. Moreover, the allegations set forth in Paragraphs 124 through 141 contain alleged findings, opinions, statements or conclusions from the "Chartbook." Fujisawa avers that the Chartbook is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations and demands strict proof thereof.

V.

142. Fujisawa admits the allegations set forth in Paragraph 142.

143. Fujisawa admits the allegations set forth in Paragraph 143.

144. Fujisawa avers that statutes and regulations that set forth the terms of Medicare reimbursement speak for themselves and are the best evidence of their contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

145. Fujisawa avers that "Medicare Explained" cited in Paragraph 145 of the Complaint speaks for itself and is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa. Fujisawa is without knowledge or information

sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

146. Fujisawa admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents.

147. Fujisawa denies the allegations in the first sentence of Paragraph 147 of the Complaint insofar as the source of the quoted material is unidentified. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 147.

148. Fujisawa avers that statutes and regulations that set forth the terms of Medicare reimbursement speak for themselves and are the best evidence of their contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

149. Fujisawa avers that statutes and regulations that set forth the terms of Medicare reimbursement speak for themselves and are the best evidence of their contents. Fujisawa further states that the Program Memo AB-99-63 cited in Paragraph 149 of the Complaint is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

150. Fujisawa states that the Program Memo AB-99-63 cited in Paragraph 150 of the Complaint is the best evidence of its contents. Fujisawa denies the remaining allegations of Paragraph 150.

151. Fujisawa admits that it has reported pricing information to various compendia. To the extent the allegations in Paragraph 151 refer to the knowledge, conduct or actions of or

benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

152. Fujisawa avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations in Paragraph 152 set forth legal arguments or conclusions of law, no response is required and none is made. Fujisawa denies the remaining allegations of Paragraph 152.

153. Fujisawa admits the allegations in Paragraph 153 of the Complaint.

154-157. Fujisawa avers that the sources cited in Paragraphs 154 through 157 of the Complaint are the best evidence of their contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

158. Fujisawa avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations in Paragraph 158 set forth legal arguments or conclusions of law, no response is required and none is made. Fujisawa denies the remaining allegations of Paragraph 158.

159. Fujisawa generally admits the factual allegations set forth in Paragraph 159 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations

are denied. To the extent the allegations in Paragraph 159 set forth legal arguments or conclusions of law, no response is required and none is made.

160. Fujisawa generally admits the factual allegations set forth in Paragraph 160 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. Fujisawa avers that the “Detailed Case Studies” cited in Paragraph 160 of the Complaint is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

161. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 161 and, therefore, denies those allegations.

162. Fujisawa admits that the reimbursement methodology for outpatient prescription drugs covered by the Montana Medicaid Program is set forth at Mont. Admin. R. 37.86.1101 *et seq.*, which is the best evidence of its contents. To the extent the allegations rely on the “Prescription Drug Program” cited in the last sentence of Paragraph 162, Fujisawa avers that it is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

163. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 163 set forth legal arguments or conclusions of law, no response is required and none is made. Fujisawa denies the remaining allegations in Paragraph 163 of the Complaint that pertain to it.

VI.

164. Fujisawa admits that AWP's play a role in various prescription drug reimbursement systems that operate in the United States. Fujisawa denies all other allegations set forth in Paragraph 164.

165. Upon information and belief, Fujisawa admits the allegations in the first two sentences of Paragraph 165 of the Complaint. Fujisawa denies all other allegations set forth in Paragraph 165.

166. To the extent the allegations in Paragraph 166 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies all other allegations in Paragraph 166.

167. Fujisawa admits that independently produced compendia periodically report AWP's for prescription medicines sold in the United States. To the extent the allegations in Paragraph 167 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 167.

168. Fujisawa admits that independently produced pricing publications periodically report AWP's for prescription medicines sold in the United States. Fujisawa states that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 168 of the Complaint are the best evidence of their contents. The remaining allegations are directed at other defendants and require no response from Fujisawa. To the extent an answer is deemed to be required, Fujisawa denies the remaining allegations in Paragraph 168 and demands strict proof thereof.

169. Fujisawa denies the allegations set forth in Paragraph 169.

170-171. Fujisawa states that the April 2003 OIG report cited in Paragraphs 170 through 171 of the Complaint is the best evidence of its content. Fujisawa denies that Plaintiff has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Fujisawa.

172. Fujisawa denies the allegations set forth in Paragraph 172.

VII.

173. Fujisawa denies the allegations set forth in Paragraph 173.

174. Fujisawa denies the allegations set forth in Paragraph 174.

175. Fujisawa denies the allegations set forth in Paragraph 175.

176. To the extent the allegations in Paragraph 176 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 176.

177. Fujisawa denies the allegations set forth in Paragraph 177.

178. Fujisawa denies the allegations set forth in Paragraph 178.

179. To the extent the allegations in Paragraph 179 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 179.

180. Fujisawa denies the allegations set forth in Paragraph 180.

181. Fujisawa denies the allegations set forth in Paragraph 181.

182. Fujisawa denies the allegations set forth in Paragraph 182.

183. Fujisawa denies the allegations set forth in Paragraph 183.

184. Fujisawa denies the allegations set forth in Paragraph 184.

185. Fujisawa denies the allegations set forth in Paragraph 185.

186. To the extent the allegations in Paragraph 186 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 186.

187. Fujisawa admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

188. Fujisawa admits that the reimbursement methodology for outpatient prescription drugs covered by the Montana Medicaid Program is set forth at Mont. Admin. R. 37.86.1101 *et seq.*, which is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

189. Fujisawa denies the allegations set forth in Paragraph 189.

190. Fujisawa denies the allegations set forth in Paragraph 190.

191. Fujisawa denies the allegations set forth in Paragraph 191.

192. Fujisawa denies the allegations set forth in Paragraph 192.

193. Fujisawa avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Fujisawa.

194. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

195. To the extent the allegations in Paragraph 195 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 195.

196. Fujisawa denies the allegations set forth in Paragraph 196.

197-200. The allegations set forth in Paragraphs 197 through 200 are directed at other defendants and no response from Fujisawa is required. To the extent an answer is deemed to be required, Fujisawa denies the allegations set forth in paragraphs 197 through 200.

201. Fujisawa denies the allegations in Paragraph 201 of the Complaint that pertain to it. To the extent the allegations in Paragraph 201 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

202. Fujisawa denies the allegations set forth in Paragraph 202 of the Complaint that pertain to it. To the extent the allegations in Paragraph 202 refer to the knowledge, conduct or

actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

203-208. Fujisawa denies the allegations set forth in Paragraphs 203 through 208 that pertain to it. To the extent the allegations in Paragraphs 203 through 208 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

209. Fujisawa denies the allegations set forth in Paragraph 209 that pertain to it. To the extent the allegations in Paragraph 209 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that THE "WALL STREET JOURNAL" article cited in Paragraph 209 of the Complaint is the best evidence of its content. Fujisawa denies that Plaintiff characterized the content of THE WALL STREET JOURNAL article accurately and specifically denies the content of the allegations referencing the article.

210. Fujisawa denies the allegations set forth in Paragraph 210 of the Complaint that pertain to it. To the extent the allegations in Paragraph 210 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

211-212. Fujisawa denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 211 of the Complaint. Fujisawa states that the September 28, 2000, letter

from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 211 through 212 of the Complaint is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to Fujisawa.

213. To the extent the allegations in Paragraph 213 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

214. Fujisawa denies the allegations set forth in Paragraph 214 of the Complaint pertaining to it. To the extent the allegations in Paragraph 214 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

215. Fujisawa denies the allegations set forth in Paragraph 215 of the Complaint pertaining to it. To the extent the allegations in Paragraph 215 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

216-409. The allegations in Paragraphs 216 through 273 of the Complaint are directed to another defendant and require no response from Fujisawa. To the extent allegations in Paragraphs 216 through 409 of the Complaint are deemed to include allegations against Fujisawa, they are denied.

410-411. The allegations set forth in Paragraph 410-11 contain Plaintiff's characterization of the action. No response is required and none is made.

412. Fujisawa admits that it reported certain pricing information for its medicines to independently produced pricing publications. Fujisawa admits that it reported a suggested AWP for its medicines during a portion of that time. Fujisawa states that FJ-MDL 015152-015159 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. The remainder of the allegations of Paragraph 412 are denied

413. Fujisawa denies the allegations set forth in Paragraph 413 of the Complaint.

414. Fujisawa states that FJ-MDL 005687-88 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. The remainder of the allegations of Paragraph 414 are denied.

415. Fujisawa states that FJ-MDL 005668-69 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. The remainder of the allegations of Paragraph 415 are denied.

416. Fujisawa states that FJ-MDL 008346 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. Fujisawa denies the remainder of the allegations of Paragraph 416.

417. Fujisawa admits that it has produced documents in response to government subpoenas, and that it often sells its products at prices below AWP. Fujisawa denies the remaining allegations in Paragraph 417 of the Complaint that pertain to it.

418. Fujisawa states that FJ-MDL 13079-81 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. Fujisawa denies the remainder of the allegations of Paragraph 418.

419. Fujisawa states that FJ-MDL 008240-53 is the best evidence of its contents and denies that the conclusions Plaintiff draws from these documents are accurate. Fujisawa denies the remainder of the allegations of Paragraph 419.

420. Fujisawa denies the allegations set forth in Paragraph 420 of the Complaint.

421. Fujisawa denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 421 of the Complaint. To the extent the allegations in Paragraph 421 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

422. To the extent the allegations in Paragraph 422 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states that the report published by the DHHS (AB-00-86) cited in Paragraph 422 of the Complaint is the best evidence of their contents, but Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained in these documents. Fujisawa denies the remaining allegations in Paragraphs 422 of the Complaint that pertain to it.

423-602. The allegations in Paragraphs 423 through 602 of the Complaint are directed to another defendant and require no response from Fujisawa. To the extent allegations in Paragraphs 423 through 602 of the Complaint are deemed to include allegations against Fujisawa, they are denied.

VIII.

603-634. Plaintiff’s “Best Price” claims against Fujisawa have been dismissed by Court Order. Accordingly, no response is required and none is made.

IX.

635. Fujisawa denies the allegations set forth in Paragraph 635 of the Complaint that pertain to it. To the extent the allegations in Paragraph 635 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

636. Fujisawa denies the allegations set forth in Paragraph 636 of the Complaint that pertain to it. To the extent the allegations in Paragraph 636 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa states the 2003 CMS document cited in Paragraph 636 of the Complaint is the best evidence of its contents. Fujisawa denies that Plaintiff has accurately characterized any alleged CMS finding, opinion, statement or conclusion.

637-640. Fujisawa denies the allegations in Paragraphs 637 through 640 of the Complaint that pertain to it. To the extent the allegations in Paragraphs 637 through 640 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

641. In response to the allegations in Paragraph 641 of the Complaint, Fujisawa denies that Plaintiff lacked inquiry or other notice of the issues associated with reliance on AWP's as a pricing benchmark. Fujisawa specifically avers, to the contrary, that such issues were well known for more than a decade before Plaintiff elected to bring this suit.

642-643. The allegations in Paragraphs 642 through 643 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Fujisawa is

without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 642 through 643 of the Complaint that refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa. Accordingly, Fujisawa denies those allegations. Fujisawa denies the remaining allegations in Paragraphs 642 through 643 of the Complaint that pertain to it.

X.

644. Fujisawa denies that Plaintiff has suffered damages or injuries as alleged in Paragraph 644 of the Complaint. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 644 of the Complaint and, therefore, denies those allegations.

645. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 645 set forth legal arguments or conclusions of law, no response is required and none is made. Fujisawa denies the remaining allegations in Paragraph 645 of the Complaint that pertain to it.

646. The allegations in Paragraph 646 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

647. Fujisawa denies the allegations set forth in Paragraph 647.

648. Fujisawa denies the allegations set forth in Paragraph 648.

649. Fujisawa denies the allegations set forth in Paragraph 649 of the Complaint that pertain to it. To the extent the allegations in Paragraph 649 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is

without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

650. Fujisawa denies the allegations set forth in Paragraph 650 of the Complaint that pertain to it.

651. Plaintiff's "Best Price" claims against Fujisawa have been dismissed by Court Order. Accordingly, no response is required and none is made.

652. Fujisawa denies the allegations set forth in Paragraph 652 of the Complaint that pertain to it.

653. Fujisawa denies the allegations set forth in Paragraph 653 of the Complaint that pertain to it.

XI.

COUNT I

Deceptive Trade Practices: **Claim for Damages Caused to Montana Residents**

654. Fujisawa realleges and incorporates its responses to the allegations in Paragraphs 1 through 654.

655. The allegations set forth in Paragraph 655 contain Plaintiff's characterization of this action. No response is required and none is made.

656. Fujisawa denies the allegations set forth in Paragraph 656 of the Complaint that pertain to it. To the extent the allegations in Paragraph 656 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their

contents. Any characterizations thereof are denied. To the extent the allegations in Paragraph 656 set forth legal arguments or conclusions of law, no response is required and none is made.

657. Fujisawa denies the allegations set forth in Paragraph 657 of the Complaint that pertain to it. To the extent the allegations in Paragraph 657 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

658. Fujisawa denies the allegations set forth in Paragraph 658 of the Complaint that pertain to it. To the extent the allegations in Paragraph 658 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

659. Fujisawa denies the allegations set forth in Paragraph 659 of the Complaint that pertain to it. To the extent the allegations in Paragraph 659 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

660. Fujisawa denies the allegations set forth in Paragraph 660 of the Complaint that pertain to it. To the extent the allegations in Paragraph 660 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Fujisawa denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count I of the Complaint.

COUNT II

Deceptive Trade Practices:
Claim for Civil Penalties, Injunctive Relief, and
Restitution for the State of Montana

661. Fujisawa realleges and incorporates its responses to the allegations in Paragraphs 1 through 660.

662. The allegations set forth in Paragraph 662 contain Plaintiff's characterization of this action. No response is required and none is made. To the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

663. Fujisawa denies the allegations set forth in Paragraph 663 of the Complaint that pertain to it. To the extent the allegations in Paragraph 663 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations thereof are denied. To the extent the allegations in Paragraph 663 set forth legal arguments or conclusions of law, no response is required and none is made. To the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

664. Fujisawa denies the allegations set forth in Paragraph 664 of the Complaint that pertain to it. To the extent the allegations in Paragraph 664 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations to the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

665. Fujisawa denies the allegations set forth in Paragraph 665 of the Complaint that pertain to it. To the extent the allegations in Paragraph 665 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

666. Fujisawa denies the allegations set forth in Paragraph 666 of the Complaint that pertain to it. To the extent the allegations in Paragraph 666 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

667. Fujisawa denies the allegations set forth in Paragraph 667 of the Complaint that pertain to it. To the extent the allegations in Paragraph 667 of the Complaint refer to the

knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against Fujisawa, those claims have been dismissed by Court Order. Accordingly, no response is required and none is made.

Fujisawa denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count II of the Complaint.

COUNT III

Medicaid Fraud:
Claim for Cost Recovery
And Civil Penalties

668-679. Plaintiff's "Best Price" claims against Fujisawa have been dismissed by Court Order. Accordingly, no response is required and none is made.

COUNT IV

False Claims:
Claim for Forfeiture, Civil Penalties,
Double Damages and Legal Costs

680-691. Plaintiff's "Best Price" claims against Fujisawa have been dismissed by Court Order. Accordingly, no response is required and none is made.

COUNT V

Punitive Damages:
Claim Brought on Behalf of the State of Montana

692. Fujisawa realleges and incorporates its responses to the allegations in Paragraphs 1 through 691.

693. Fujisawa denies the allegations set forth in Paragraph 693 of the Complaint that pertain to it. To the extent the allegations in Paragraph 693 of the Complaint refer to the

knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Fujisawa denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count V of the Complaint.

XI.

Fujisawa denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief.

DEFENSES

First Defense

Plaintiff fails to state a claim against Fujisawa upon which relief may be granted.

Second Defense

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Fujisawa as alleged in the Complaint.

Fourth Defense

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against Fujisawa based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

Fifth Defense

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana.

Sixth Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

Seventh Defense

Any and all actions taken by Fujisawa with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Eighth Defense

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Ninth Defense

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

Tenth Defense

Plaintiff's claims against Fujisawa are barred because Fujisawa has complied with all applicable regulations of the federal and state governments.

Eleventh Defense

Plaintiff's claims against Fujisawa are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

Twelfth Defense

Plaintiff's claims are barred, in whole or in part, because they violate Fujisawa's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Thirteenth Defense

Fujisawa's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

Fourteenth Defense

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi-source medicine allegations against Fujisawa contained in the Complaint.

Fifteenth Defense

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited, to Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

Sixteenth Defense

Plaintiff fails to allege with particularity its civil conspiracy claims against Fujisawa as required by FED. R. CIV. P. 9(b).

Seventeenth Defense

Plaintiff's claims against Fujisawa are barred because Fujisawa did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

Eighteenth Defense

Plaintiff's claims against Fujisawa are barred, in whole or in part, because Fujisawa did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against Fujisawa that Plaintiff alleges to be false or misleading, Fujisawa had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Nineteenth Defense

Plaintiff's claims against Fujisawa are barred because Fujisawa did not directly or indirectly engage in any conduct in violation of state or federal law.

Twentieth Defense

Fujisawa denies that Plaintiff has valid consumer protection claims against Fujisawa under Montana state law. However, if such claims are found to exist, Fujisawa pleads all available defenses under the applicable laws.

Twenty-First Defense

Any allegedly fraudulent statements or conduct of Fujisawa did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Montana.

Twenty-Second Defense

Fujisawa's conduct was not "deceptive" as required under Montana consumer protection laws.

Twenty-Third Defense

To the extent that Plaintiff seeks equitable relief against Fujisawa, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

Twenty-Fourth Defense

Plaintiff did not rely on the allegedly fraudulent statements or conduct of Fujisawa as required under the Montana consumer protection laws.

Twenty-Fifth Defense

Any allegedly fraudulent statement or conduct of Fujisawa was not consumer-oriented as required under the Montana consumer protection laws.

Twenty-Sixth Defense

Plaintiff's claims against Fujisawa for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Twenty-Seventh Defense

Some or all of Plaintiff's claims for injunctive relief against Fujisawa are barred by the doctrines of *in pari delicto* and/or unclean hands.

Twenty-Eighth Defense

Some or all of Plaintiff's claims against Fujisawa arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

Twenty-Ninth Defense

Plaintiff's claims against Fujisawa are barred, in whole or in part, due to its failure to join indispensable parties.

Thirtieth Defense

Plaintiff's claims against Fujisawa are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

Thirty-First Defense

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

Thirty-Second Defense

Plaintiff's claims against Fujisawa for damages are barred, in whole or in part, because: (1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Fujisawa; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Fujisawa after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Thirty-Third Defense

Fujisawa is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

Thirty-Fourth Defense

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from Fujisawa.

Thirty-Fifth Defense

Plaintiff fails to allege facts or a cause of action against Fujisawa sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

Thirty-Sixth Defense

Plaintiff's punitive damages claims against Fujisawa: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Fujisawa; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Fujisawa prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Fujisawa's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Montana; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Montana; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Fujisawa for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Fujisawa's medicines, would constitute impermissible multiple punishments for the same wrong in violation of Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Montana; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally

between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Fujisawa the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Fujisawa's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana.

Thirty-Seventh Defense

Plaintiff's claim for punitive damages against Fujisawa cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of Fujisawa; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden

of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Fujisawa's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Montana.

Thirty-Eighth Defense

Plaintiff's claim for punitive damages against Fujisawa cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Fujisawa's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Fujisawa's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Montana.

Thirty-Ninth Defense

Fujisawa adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein.

Fortieth Defense

Fujisawa hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, Fujisawa respectfully demands judgment dismissing the Complaint in its entirety and awarding it the costs and disbursements of this action, as well as such other and further relief as this Court deems just and proper.

Respectfully Submitted,

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Attorneys for Defendants Fujisawa
USA, Inc. and Fujisawa Healthcare,
Inc.

Dated: July 12, 2004

CERTIFICATE OF SERVICE

I certify that a true and correct copy of Fujisawa Healthcare, Inc. and Fujisawa USA, Inc.'s Answer To State of Montana's Second Amended Complaint was delivered to all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending, on July 12, 2004, a copy to Verilaw Technologies for posting and notification to all parties.

/s/ Andrew L. Hurst

Andrew L. Hurst